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IRB BRANCH REVIEW - TSS

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EFFICACY

FILE OR REG. NO. 46779-1

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 7/23/91

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TYPE PRODUCTS(S): I, D, H, F, N, R^x, S _____

DATA ACCESSION NO(S). none

PRODUCT MER. NO. 14

PRODUCT NAME(S) SODIUM FLUOROACETATE (COMPOUND 1080) LIVESTOCK PROTECTION COLLAR

COMPANY NAME Ranchers Supply, Inc.

SUBMISSION PURPOSE Discuss 1990 monitoring report and future requirements
for such reports

CHEMICAL & FORMULATION 1.00% Sodium Fluoroacetate (Compound 1080)
solution in Livestock Protection Collar

Efficacy Review: SODIUM FLUOROACETATE (COMPOUND 1080) LIVESTOCK PROTECTION COLLAR,
46779-1
Rancher's Supply, Inc.
Alpine, TX 79831

200.0 INTRODUCTION

200.1 Use

A 1.00% Sodium Fluoroacetate (Compound 1080) solution enclosed in a two-pouched rubber vessel attached to Velcro bands which hold the pouches in place in the throat regions of sheep or goats subject to predatory attacks by coyotes.

200.2 Background Information

See efficacy reviews of 11/21/86, 7/7/87, 7/11/88, 9/9/88, 11/15/88, 3/5/89, 4/29/89, 6/13/89, 12/19/89, 5/9/90, 10/22/90, 1/25/91, 3/1/91, and 5/20/91, along with other information in the three-volume product jacket.

The product was conditionally registered on 12/1/87. Rancher's Supply is the source for all Livestock Protection Collars legally produced in this country. The name of the president of Ranchers Supply, Roy McBride, has been mentioned in press accounts of a recent "sting" operation in Wyoming and Colorado which culminated in a raid on several facilities and apparent charges against an employee of the Wyoming Department of Agriculture. It is not at all clear from these accounts whether McBride can or will be charged with any crimes as a result of these investigations.

This review discusses the the Texas Department of Agriculture's (TDA's) reply to EPA's letter of 6/12/91 which addressed TDA's "1990 Annual Report Livestock Protection Collar Use," and amended version of the 1990 annual report, and TDA's proposal to be relieved of future requirements to file monitoring reports. TDA's letter was written prior to the "sting" operation and may be related to circumstances that are totally separate from that investigation. Nevertheless, it seems impossible to ignore the types of offenses alleged in the investigation in the sense that the policies followed in or proposed for Texas should be explored for the "room" they might leave for serious abuse.

201.0 DATA SUMMARY

The amended annual report includes an amended version of the original report's "Table 1." That table has been

"... corrected to remove some discrepancies from typing errors and to reflect some additional information on fate of collars that came to light after preparation of the original report."

TDA reports that 197 persons either were licensed or relicensed in 1990 to use Livestock Protection Collars in the Lone Star State. A total of 1183 collars were purchased in Texas in 1990. Individuals purchased 220 collars; pools bought 663; and the Texas Animal Damage Control (ADC) Service bought 300 collars.

Of the licensed applicators in Texas, 39 reported use of collars in 1990, while 26 reportedly stored collars but did not use them. Eight of the applicators using collars in Texas in 1990 were ADC personnel.

General data on collar use in Texas in 1990 are summarized in Table A., which has been constructed to permit comparisons between results reported for ADC use and for use by ranchers. Comparing Table A. in this report with Table 1. in the efficacy review of 5/20/91 indicates some changes to the 1990 annual report in the information that I was able to extrapolate from the two versions. The data on numbers of counties where ranchers used collars are somewhat suspect as it is possible that, in some of these counties, collars were stored but not used. The most important change attributable to TDA is the increase from 23 to 28 in numbers of rancher-used collars that were believed to have been punctured by coyotes. The data in TDA's Table 1, now match the total of such coyote punctures reported in texts of both versions of the report. Several collars were double-listed in the earlier report (as "lost" and as damaged by "other causes"). Collar "0848," used in Swisher County, was listed in the new report as "lost" and as "punctured" by a coyote.

Table B compares results reported for 1990 with those reported for 1988 and 1989, and has been updated to reflect TDA's amended annual report for 1990. The amended table shows the upturn in collar use in 1990 more clearly than did the earlier version. This increase appears to have been due to the advent of collar pools and to the beginnings of use of collars by Texas ADC personnel.

There were no apparent changes to TDA's attachment reporting on collar pools in the amended annual report. In response to EPA's inquiry, Murray Walton of TDA writes in his cover letter that pool agents do not file periodic reports but report collar transfers as they occur. Individual applicators, whether members of pools or not, remain responsible for quarterly reports. Walton reports that pool agents have helped applicators in writing quarterly reports.

Using somewhat convoluted logic, Walton states that he does not feel that it is necessary to amend Section I of the technical bulletin even though TDA's quarterly report for 1990 indicates that the approach of placing a few collared lambs in a large flock of adult sheep has been used as an effective targeting strategy in Texas. The technical bulletin currently suggests this type of approach for use with goats but specifically says that it is not recommended for sheep. Walton argues that general statements in the bulletin to the effect that knowledge of targeting is in its infancy and that ranchers should use as few collars as possible would make the strategy acceptable for sheep. Walton also expresses concern that making the change might cause ranchers to use too few collars in many instances and, therefore, be "counter productive." I agree that the current bulletin does not prohibit use of this strategy for sheep, but feel that the bulletin should not discourage this approach if it has been used successfully. Whether the change is to be made ultimately is the registrant's decision.

Walton responds to EPA concern that dropping the monitoring program might remove EPA's best handle on possible hazards to Endangered Species by stating

Table A. Summary of Livestock Protection Collar use in Texas in 1990.

	USAGE BY POOLS AND INDIVIDUALS	TEXAS ADC USAGE	1990 TOTALS
Applicators Using Collars	31	8	39
Counties Where Collars Used	32	17	36
Days of LPC Use			
Maximum	22,163	14,470	36,633
Minimum	22,597	14,702	37,299
Average	22,382.5	14,586	36,966
Collars Punctured by Coyotes	28*	10	38*
Collars Damaged by Vegetation	23	7	30
Collar Damaged by Other Causes	13	NR	13?
Collars Damaged by Unknown Causes	1	8	9
Collars Lost	34*	11	45*
Coyotes Believed to Have Been Taken by Collars	24	7-10	31-34
Suspected Collar Kills Found	6	NR	6?
Nontarget Deaths Reported	0	0	0
Violations Reported	0	0	0

* One collar serial number (0848) was listed both as punctured and as lost.

Table B. Summary of Livestock Protection Collar use in Texas in 1988-1990.

	1988 TOTALS	1989 TOTALS	1990 TOTALS
Collars Bought	827	441	1183
Applicators Using Collars	34	30	39
Counties Where Collars Used	22	20	36
Days of LPC Use			
Minimum	24,944	25,543	36,633
Maximum	26,445	28,428	37,299
Average	25,694.5	26,985.5	36,966
Total Collars Used	524	463	≤ 951¶
Collars Apparently Undamaged*	435	380	820
Collars Punctured by Coyotes	30	23	38
Collars Damaged by Vegetation	15	28	30
Collars Damaged by Other Causes	1	0	13?§
Collars Damaged by Unknown Causes	4	7	9
Collars Lost	39	25	45
Coyotes Believed to Have Been Taken by Collars	37	23	31-34
Suspected Collar Kills Found	7	1	6?
Nontarget Deaths Reported	1†	0	0
Prey Kills w/no Collar Puncture	1	26	NR
Serious Infractons Reported	1	1	0

¶ The number of collars used by ADC personnel was not reported. This figure represents the maximum possible number of collars used.

* This number determined by subtracting numbers in "damaged" and "lost" categories from total number of collars used.

§ Twelve of these collars may have been the ones that were reportedly disposed of for being "in poor condition."

† This animal was a lamb whose collar had been ruptured by unknown causes.

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"We believe that such consideration is already addressed in several ways: 1) the formulation of Compound 1080 in the collar is of a concentration that is highly unlikely to result in secondary poisoning of the few scavengers that will feed on dead coyotes; 2) the training program required of all applicators advises of Endangered Species considerations; 3) mandated weekly checks of collared livestock and disposal requirements remove possible hazards; 4) any nontarget kills must be reported (to date only one lamb and one kid goat wearing collars have been suspected to have been accidentally poisoned); and 5) collar use in Texas has not been in areas of susceptible Endangered Species."

Walton's point "1)" is clearly false. The concentration of 1080 in collars is 9+ times that (0.11% 1080) which traditionally was used in 1080 field rodenticide baits and which has been shown to have produced secondary poisoning. Research on collars to date has shown that dead collared animals and collar-killed coyotes can retain enough 1080 to kill scavengers. It is true that very few nontarget kills have been associated with operational and experimental use of Livestock Protection Collars, but it is not fair to minimize the potential for such incidents. The chief advantage of the collar is its ability to target specific "offending" individual coyotes intent on killing lambs or kids with bites to the throat region.

Walton's points "2)" and "3)" refer to various "checks" against significant nontarget hazards which have been built into collar labeling and into certification and training programs for collar use. Walton's point "4)" is offered as evidence that the training and labeling are having their desired effects -- the only known nontarget kills in TDA's program were livestock slated for death anyway as collar wearers.

Walton's point "5)" merits extended discussion. None of the Endangered Species identified in the Fish & Wildlife Service's (FWS's) "Biological Opinion" of 6/14/85 occur in Texas. In that document, FWS concluded that bald eagles were not at risk if collars were used as proposed. The "Use Restrictions" portion of the technical bulletin for 46779-1 currently identifies no counties in Texas where the collar cannot be used due to concerns for Endangered Species and names no specific species. Ocelots and jaguarundis occur in several counties in southeastern Texas along the Rio Grande.¹ These species were listed in the technical bulleting originally accepted for 46779-1, but EPA's acceptance letter of 12/1/87 specifically required that all counties, including 12 from Texas, which were listed in the proposed technical bulletin be deleted from the "Use Restriction ("6.") which deals with Endangered Species.

¹ Attwater's prairie chickens occur and whooping cranes winter in several counties along the gulf coast and somewhat inland. These species are quite unlikely to be exposed to 1080 used in collars. The 12 counties once listed in proposed technical bulletins are those where ocelots, jaguarundis, prairie chickens, or whooping cranes may occur.

Walton seems to imply that EPA's argument that the monitoring program might have to be continued indefinitely due to Endangered Species concerns is a bit of a "red herring," given previous determinations regarding Texas. It is noteworthy, however, that some of the data upon which FWS based its opinion were declared invalid and that improved assay procedures at the Denver Wildlife Research Center (DWRC, USDA/APHIS) have indicates that 1080 residues in various tissues may be much higher than originally thought. Therefore, the basic conclusion of no hazard to bald eagles may not have been accurate. The monitoring report requirement at least gives the appearance that there is a mechanism in place to ensure that detected bald eagle kills are reported.²

Walton also notes that TDA's proposes to end requirements for official reporting ("quarterly applicator report, site review form, and annual report requirements"), not to discontinue monitoring. What would be continued would be applicators' record keeping requirements and TDA's annual inspections. Walton concludes

"Such monitoring should be sufficient to identify any problems that might arise."

It is very tempting to concur. TDA is in the fourth year of a monitoring program. There was some thinking within EPA that continued needs for monitoring programs would be examined after four years' worth of reports were submitted. Current "Use Restrictions," certification and training programs, and regulatory surveillance by TDA may be adequate to regulate collar use in Texas. TDA has identified some violations in the past but might have detected the same violations if quarterly reports by applicators and annual reports to EPA had not been required. Instead of annual reports, EPA could require that TDA furnish EPA with synopses of significant future incidents. Several of the violations reported by TDA apparently were committed by Ranchers Supply itself (see discussions in prior efficacy reviews). It should be noted that all known violations occurred with the current monitoring and reporting requirements in place.

It also should be noted that Compound 1080 has been used in ways other than in Livestock Protection Collars to kill coyotes and other animals. At this time, all uses of 1080 except in the collar are illegal in the U.S. The "sting" was intended to catch people who wanted to use 1080 and other chemicals illegally to kill predators. While such acts are criminal and, therefore, not prevented by laws and regulations, it must be recognized that, with ranchers' frustrations with current methods for controlling predation being acute, the temptation for doing illegal things may be very great for some individuals. Tight accounting of 1080 from legal sources might reduce temptations to channel that material into illegal use.

² One of the charges in the "sting" case is that illegal transfer of 1080 to various individuals was responsible for the killing of substantial numbers of bald eagles. It appears, however, that the most or all of such eagles would have been exposed to 1080 from carcass baits, rather than to 1080 from toxic collars worn by livestock in the field.

While it would be absurd to argue that required accounting of every gram of legal 1080 (an unlikely event even under current requirements) sold would preclude the existence of illegal trade in 1080, it seems useful to hold manufacturers, registrants, dealers (pool agents), and users accountable for the 1080 and collars purchased by or entrusted to them. Many of the incidents alleged pursuant to the "sting" operation are believed to have involved an individual employed by a registrant which EPA had trusted to fill, distribute, and dispose of collars; to train and certify applicators, and to serve as the lead agency for monitoring collar use and enforcing against misuse.

I feel that the issue in Texas is more whether the registrant, the dealers, and the users can be trusted than whether TDA can be trusted. I conclude this based upon my past experiences with TDA and its record for identifying problems and violations and dealing with them promptly. TDA is largely responsible for Ranchers Supply's on-paper compliance with the conditions of its registration for the Livestock Protection Collar. If Ranchers Supply emerges "clean" from investigations associated with the "sting," EPA should seriously consider TDA's proposal for terminating the monitoring report requirement. In the meantime, we should continue dialogue with TDA on this matter.


202.0 CONCLUSIONS

Thank you for your letter of July 5, 1991, and the amended version of your report "1990 ANNUAL REPORT LIVESTOCK PROTECTION COLLAR USE." Numbers seem to track much better between text and tables in the revised version.

We understand your basic points concerning the checks on potential abuse of the collar that would remain in labeling, training, and monitoring if we dropped the requirement for the Texas Department of Agriculture to submit annual monitoring reports for Ranchers Supply's Livestock Protection Collar. Are we correct in assuming that the site review form that would be dropped would be that used by the "Registrant or Agent" and not the form used by your Department in its inspections? It seems to us that having a form to fill out would promote completeness and consistency in inspections.

We do not agree with your statements to the effect that the concentration of Compound 1080 used in the collar renders secondary poisoning unlikely if scavengers feed on collar-killed coyotes. As the concentration of 1080 in the collar solution is more than nine times the 0.11% concentration used in rodenticide baits shown to cause secondary poisoning, we conclude that the collar solution is capable of producing a very "hot" coyote carcass if the predator ingests a significant amount of the liquid. Punctured collars also leave "hot" areas on lamb or kid carcasses that would be available to scavengers until it is located and disposed of by the applicator.

Recent data and investigations have called into question some of the data upon which was based the original determination that collars pose minimal risks to bald eagles. As the eagle hazard study could not be replaced by a new one, the annual monitoring report came to be viewed by EPA as a mechanism through which nontarget incidents could be tallied as indices to potential problems that might require remedial action through labeling changes. In your



letter of July 5, 1991, you suggest that current training programs and label requirements are sufficient to insure that users are aware of potential problems and that incidents that do occur are reported promptly. Although we can see how training and reporting requirements might serve to limit risks to Endangered Species, we are not yet persuaded that such would always be the case.

While we have no indications that the Texas Department of Agriculture has been anything other than thorough and forthright regarding the regulation and use of the Livestock Protection Collar, the monitoring report is concerned primarily with the activities of the registrant, the registrant's agents, and the users themselves. Given that the toxicant used in the collar has a prior history of use in other delivery systems to control coyotes and that there is potential interest in rerouting 1080 designated for collars into these now-illegal delivery systems, EPA is very concerned that there be strict accounting for the 1080 transferred in legal channels of trade.

If you continue to monitor users, agents, and the registrant and agree to report all significant problems that occur as they arise, it might be possible to dispense with the formal annual reporting requirement once reports for the first four years of use have been provided. Note that we are raising this approach as a possibility at this time but have not reached a final decision on its adequacy. We would appreciate your thoughts on this approach.

William W. Jacobs
Principal Specialist: Rodenticides
Insecticide-Rodenticide Branch
October 15, 1991

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